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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,222	04/06/2004	Daniel J. Lubich	DEKA:341US	7117
32425	7590	06/17/2005	EXAMINER	
FULBRIGHT & JAWORSKI L.L.P.			FOX, DAVID T	
600 CONGRESS AVE.			ART UNIT	
SUITE 2400			PAPER NUMBER	
AUSTIN, TX 78701			1638	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,222	LUBICH, DANIEL J.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/23/04</u> . | 6) <input type="checkbox"/> Other: ____. |

48

Art Unit: 1638

The specification is objected to on page 22 ; and claims 1-2, 9, 11-13, 17-19 and 23 are objected to; for their inclusion of blank lines. It is assumed that the blanks will be replaced with the ATCC deposit accession number.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 11, 15-16 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claim 6 is confusing in its recitation of "corn plant of claim 2, further comprising a nuclear or cytoplasmic gene conferring male sterility", which simultaneously characterizes the male fertile plant of claim 2 as somehow being concurrently male sterile. Replacement of claim 6 with a process claim for conferring male sterility to the plant of claim 2, followed by a product-by-process claim, would obviate this rejection.

Claim 11 is indefinite in its recitation of "capable of", as it is unclear whether or not the corn plant does or does not actually express the physiological and morphological characteristics of the exemplified corn inbred, at any developmental stage or in any environment. Replacement of "capable of expressing" with ---expressing---, as recited in claim 5, would obviate this rejection.

Claim 15 is confusing in its recitation of "corn plant of claim 2, further comprising a transgene", which simultaneously characterizes the plant of claim 2, with a defined

Art Unit: 1638

and finite genome, as somehow concurrently comprising an additional transgene. See the discussion of claim 6 above.

Claim 19 is indefinite in its recitation of "said genome... comprising the genetic locus" which is confusing, as a locus is a position on a genome rather than a piece of DNA or a gene. See claim 19, part (a), last two lines; part (b), last two lines; part (c), last two lines; part (d), last two lines; and part (e), last two lines.

Claim 20 is indefinite in its recitation of "genetic locus was stably inserted into a corn genome" which is confusing, as a locus is a position on a genome rather than a piece of DNA or a gene. Furthermore, it is unclear whether the locus was inserted into the genome of the corn plant of claim 20, or some other corn plant, given the recitation of "a genome". Replacement of "a" with ---the--- would obviate this aspect of the rejection.

Claim 21 is indefinite in its recitation of "yield enhancement", "improved nutritional quality", and "enhanced yield stability", as "enhanced" and "improved" are relative terms which do not clearly specify the degree of trait expression.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants intend to deposit the plant but there is no indication in the specification on page 22 as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Claims 6, 11, and 15-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 is broadly drawn to any plant comprising a male sterility trait introgressed into the claimed variety by backcrossing or other traditional means, wherein said plant is simultaneously male fertile. Claim 11 is broadly drawn to a multitude of somaclonal variants of the exemplified corn inbred, with a multitude of mutations at a multitude of genetic loci. Claims 15-17 and 20 are broadly drawn to any plant which contains any heterologous transgene of any sequence conferring any trait, including the traits of "yield enhancement" and "improved nutritional quality", and methods of making the resultant plants. Claims 18-23 are drawn to methods of making and using any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with

Art Unit: 1638

undisclosed breeding partners, without selecting for traits of the exemplified inbred cultivar (and therefore selecting for the retention of the genome of the exemplified inbred cultivar) at each breeding step; wherein the second parent contains an undefined gene or genes of any sequence conferring any trait; and the resultant "converted" plants. Claims 23-24 are broadly drawn to any hybrid plant produced by crossing the exemplified inbred line with any of a multitude of non-exemplified plants.

No guidance has been provided for the description or characterization of a multitude of heterologous coding sequences conferring a multitude of traits, including yield enhancement and improved nutritional quality. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny. Guidance has only been provided for a method of using the exemplified inbred cultivar in a process for producing a single F1 hybrid.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed

subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description

Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Claims 6, 11, and 15-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 6 is broadly drawn to any plant comprising a male sterility trait introgressed into the claimed variety by backcrossing or other traditional means, wherein said plant is simultaneously male fertile. Claim 11 is broadly drawn to a multitude of somaclonal variants of the exemplified corn inbred, with a multitude of mutations at a multitude of genetic loci. Claims 15-17 and 20 are broadly drawn to any plant which contains any heterologous transgene of any sequence conferring any trait, including the traits of "yield enhancement" and "improved nutritional quality", and methods of making the resultant plants. Claims 18-23 are drawn to methods of making and using any

Art Unit: 1638

descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners, without selecting for traits of the exemplified inbred cultivar (and therefore selecting for the retention of the genome of the exemplified inbred cultivar) at each breeding step; wherein the second parent contains an undefined gene or genes of any sequence conferring any trait; and the resultant "converted" plants. Claims 23-24 are broadly drawn to any hybrid plant produced by crossing the exemplified inbred line with any of a multitude of non-exemplified plants.

No guidance has been provided for the isolation or characterization of a multitude of heterologous coding sequences conferring a multitude of traits, including yield enhancement and improved nutritional quality. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny, or their use. Guidance has only been provided for a method of using the exemplified inbred cultivar in a process for producing a single F1 hybrid.

Corn breeding is unpredictable, due to linkage drag, epistasis, quantitative inheritance of traits such as yield enhancement, and the lack of any predictable characteristics of hybrids produced by a particular cultivar as one parent.

Murray et al teach that linkage drag is a common phenomenon in corn breeding, and that the equivalent of 10 backcrosses resulted in the retention of 10% of the unwanted donor parent genome, in contrast to the predicted less than 1% (see, e.g., pages 82-84). Thus, outcrosses to produce single locus conversion plants would also introgress unwanted linked genetic material from the donor parent. In the absence of repeated generations of backcrossing *and* selection for the recipient parent's traits, this unwanted genetic material would never be lost, and the claimed "single gene conversion" plants could not in fact be produced.

Furthermore, the use of breeding crosses to obtain a particular desirable corn individual possessing a particular genetic and morphological complement of traits is unpredictable, due to the large number of genes involved, and the interaction of these genes with selection methods, environmental effects, breeder actions. See Kevern (US 5,850,009, column 4, lines 37-46). Moreover, the usefulness of a multitude of hybrids produced by crossing a single inbred with a multitude of non-exemplified breeding partners is unpredictable, given the polygenic nature of inheritance of many agronomic traits, the difficulty in predicting the expression of said traits in hybrid progeny of inbreds which do not express them, and the failure of those collections of traits to be transmitted to progeny of parents containing them (see, e.g., US 5,763,755 to Carlone, paragraphs bridging columns 1 and 2).

In addition, many value-added traits such as “yield enhancement” or “improved nutritional quality” are conferred by multiple genes, or quantitatively inherited, wherein such traits are incorporated into a desired genetic background via molecular markers. However, the use of molecular markers in corn breeding is unpredictable. Goldman et al teach that the use of molecular markers to facilitate the identification of chromosomal regions associated with quantitatively inherited traits in corn is hampered by the different linkage maps generated when different breeding lines are used as parents (see, e.g., page 909, column 2, top paragraph; paragraph bridging pages 911 and 912; paragraph bridging pages 912 and 913). In addition, inconsistent results were observed regarding the correlation of particular quantitatively inherited traits (see, e.g., Goldman et al, page 910). Furthermore, quantitative traits such as oil or protein content are inversely proportional to kernel size in corn (see, e.g., Goldman et al, page 908, column 1, middle paragraph and column 2, bottom paragraph).

Murray et al also teach the unpredictability inherent in molecular marker-assisted breeding or pedigree determination in corn, given the failure to identify molecular markers which are actually specific for particular corn cultivars (see, e.g., page 79, second full paragraph).

In addition, corn breeding is confounded by unpredictable epistatic effects, including genetic interactions and environment X genotype interactions, which prevent the prediction or recovery of plants with desirable increases in yield and other agronomic traits. Stuber et al teach that grain yield and ear number were strongly affected by environmental influences such as plant density, and that epistatic genetic

Art Unit: 1638

interactions prevented accurate performance prediction of particular hybrids derived from particular crosses (see, e.g., page 503, Abstract; page 505, column 1, first and third full paragraphs; page 506, paragraph bridging the columns). Melchinger et al teach that epistatic effects reduced the amount of heterosis (hybrid vigor measured by increased grain yield and overall plant health) in hybrid crosses (see, e.g., page 231, column 1, bottom paragraph; column 2, first paragraph of Introduction; page 233, column 2, bottom paragraph; page 237, column 1, top paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate the genes responsible for a multitude of non-exemplified traits, to evaluate the ability of these genes to be successfully expressed in various maize genetic backgrounds, or to obtain "single gene conversion" plants which contain a multitude of introgressed traits, but otherwise maintain all of the genetic and physiological and morphological characteristics of the parent plant. Undue experimentation would have also been required to evaluate a multitude of hybrids produced by a multitude of non-exemplified breeding partners for their genetic and morphological constitutions, and to determine a use for each.

Amendment of claim 11 to overcome the indefiniteness rejection would obviate the rejections of that claim under 35 USC 112, first paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1638

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Bockelman (US 6,420,637).

Claim 11 is drawn to a plant which is "capable of" expressing all of the physiological and morphological characteristics of the exemplified corn inbred.

Bockelman teaches a corn plant which expresses the following morphological traits expressed by the exemplified corn inbred: absent stalk anthocyanin, straight internode, dark green leaves, light sheath pubescence, few longitudinal creases, green glume, absent glume band, upright ear, semi-conical ear, yellow silk, short husk bract, green fresh husk color, buff dry husk color, red cob, straight row direction, yellow cap color, and normal endosperm (see Table 3 bridging columns 14 and 15).

Accordingly, Bockelman teaches a plant which is "capable of" expressing the morphological traits of the exemplified inbred.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claims 1-10 and 12-24 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a corn plant with the unique genetic and morphological complement of the exemplified inbred, or methods of its use in a breeding program. The closest prior art, Bockelman, teaches a corn plant which differs from the exemplified corn plant in at least the following characteristics: moderate brace root color, basal-weak sheath anthocyanin, pink anther, few marginal waves, intermediate husk opening, pale-yellow side and endosperm color.

No claim is allowed.

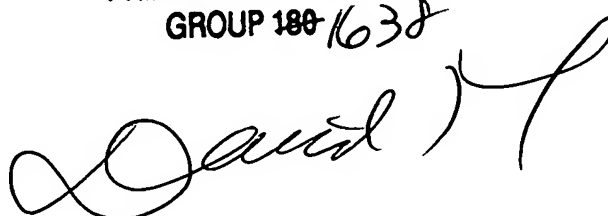
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson, Ph.D., can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 13, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and group number.